Developing Signs of Safety: A Deaf-accessible counselling toolkit for trauma and addiction


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Funding information
National Center for Advancing Translational Sciences, Grant/Award Number: KL2TR000160; National Institute on Alcohol Abuse and Alcoholism, Grant/Award Number: R34AA026929

Abstract
The U.S. Deaf community—more than half a million Americans who communicate using American Sign Language (ASL)—experiences higher rates of trauma exposure and substance use disorder (SUD) than the general population. Yet there are no evidence-based treatments for any behavioural health condition that have been evaluated for use with Deaf people. The driving aim of our work, therefore, has been to develop and formally evaluate a Deaf-accessible trauma/SUD counselling approach. Here we describe our initial intervention development work and a single-arm pilot that evaluated the feasibility, acceptability, and preliminary clinical efficacy of Signs of Safety—a Deaf-accessible toolkit to be used with an existing, widely adopted protocol for trauma and addiction (Seeking Safety). Preliminary efficacy results indicated clinically significant reductions in PTSD symptoms and frequency of alcohol use for the Seeking Safety/Signs of Safety model. Frequency of drug use did not change significantly—likely attributable to the mid-study legalization of recreational marijuana in our state. Next steps include the redesign and refilming of Signs of Safety based on pilot participant feedback, again using a Deaf-engaged development and production process. This new toolkit will be tested via a pilot randomized controlled trial designed based on present methodological lessons learned.

KEYWORDS
community engagement, Deaf, evidence-based therapy, substance use disorder, trauma

INTRODUCTION

The U.S. Deaf community—a sociolinguistic minority group of more than half a million Americans who communicate using American Sign Language (ASL; Mitchell et al., 2006)—experiences higher rates of trauma exposure and substance use disorder (SUD) than the general population. One factor that may contribute to such disparities is a current lack of Deaf-accessible evidence-based therapies to prevent and/or treat these conditions.

1.1 Behavioural health disparities

Deaf Americans are twice as likely to experience lifetime and past-year trauma exposure compared with individuals in the general population (Anderson et al., 2011; Anderson & Leigh, 2011; Black & Glickman, 2006; Porter & Williams, 2011; Schild & Dalenberg, 2012). Approximately 25% of hearing women report lifetime prevalence of domestic violence: this figure surpasses 50% among Deaf women (Anderson et al., 2011; Anderson & Leigh, 2011; Pollard et al., 2014;
Porter & Williams, 2011). Striking disparities between Deaf and hearing populations have also been documented for rates of sexual assault, sexual harassment, and child abuse (Barber et al., 2010; Francavillo, 2009; Sebald, 2008).

Similar behavioural health disparities are observed for prevalence of SUD. Community samples of Deaf people report nearly three times the rate of lifetime problem drinking compared with the U.S. general population (33.0% vs. 12.3%) and are more likely to be regular marijuana users (35.8% vs. 26.7%; Anderson et al., 2018). Additionally, Deaf psychiatric inpatients experience higher rates of polysubstance abuse (9.4% vs. 4.4%) and polysubstance dependence (6.3% vs. 1.1%) compared with hearing inpatients (Black & Glickman, 2006).

When trauma and SUD co-occur, the treatment course becomes increasingly complex (Najavits et al., 2017). Among Deaf youths receiving SUD treatment, 74% report lifetime and 44% report past-year physical, emotional, or sexual abuse (Titus et al., 2008). Although little is known about the functioning of Deaf clients with this particular comorbidity, hearing individuals with comorbid trauma and SUD have greater physical and social impairment, higher rates of mood, anxiety, and personality disorders, and increased substance craving in response to trauma symptoms compared with those with SUD alone (Coffey et al., 2006; Riggs et al., 2003; Sannibale et al., 2013).

### 1.2  Best practices in Deaf mental health

Given that most Deaf clients who enter behavioural health treatment have trauma histories and at least 74% of Deaf individuals in SUD treatment have experienced abuse (Titus et al., 2008), implementing integrated trauma/SUD interventions for this population is a logical first step to address Deaf behavioural health disparities in the United States. However, currently available evidence-based psychotherapies were designed for hearing populations and therefore fail to meet the unique linguistic, developmental, and cultural needs of Deaf clients (Anderson et al., 2017b; Estrada & Beyebach, 2007; Fellinger & Fellinger, 2014; Glickman & Pollard, 2013; Kuenburg et al., 2016; Skot et al., 2017). Most combine traditional talk therapy with client workbooks or handouts, which often contain sophisticated strategies for tracking mood, behaviour, and thoughts, and use psychological jargon throughout. To meet the linguistic needs of Deaf clients, these written English client materials require substantial plain text revisions or translations into ASL (Glickman, 2009a; McKee et al., 2015). As noted above, Deaf people’s primary language is ASL. Many Deaf individuals learn written English as a second language. As such, the median reading level of Deaf high school graduates falls at a fourth grade equivalent (Mayer & Trezek, 2020; Morere, 2011).

Low health literacy is also common due to limited language access during key developmental periods and “a lifetime of limited access to information that is often considered common knowledge among hearing persons” (Barnett et al., 2011, p. 1; Gur et al., 2020; Kushalnagar et al., 2018; Naseribooriabadi et al., 2017). Health-related vocabulary among Deaf sign language users parallels non-English-speaking U.S. immigrants, and “many adults Deaf since birth or early childhood do not know their own family medical history, having never overheard their hearing parents discussing this with their doctor” (Barnett et al., 2011, p. 1; Kushalnagar et al., 2018). Many Deaf clients have little understanding of recovery concepts—for example, substance, relapse, trigger (Anderson et al., 2016)—and do not identify being hit, choked, or coerced into sex as abuse (Anderson & Kobek Pezzarossi, 2012).

Equally important are treatment materials that increase clinician cultural competence and enhance client engagement by being inclusive of Deaf values and social norms, acknowledging Deaf people’s history of oppression within the hearing world, and embracing Deaf people’s identity as a cultural—not disability—group (Díaz & Goyal, 2020; Glickman, 2009a; Ladd, 2003; Malebranche et al., 2020; Pollard et al., 2009). Whereas clinicians often adopt a medical view of “hearing impairment,” most Deaf clients do not view themselves as “impaired,” but as members of a rich community with shared experience, history, and culture (Bauman, 2004; Díaz & Goyal, 2020; Ladd, 2003; Lane, 1992; Malebranche et al., 2020). This theoretical disconnect between many hearing clinicians and Deaf clients fuels a sense of mistrust that can lead to reductions in help-seeking behaviour, treatment retention, and overall treatment efficacy (Anderson et al., 2016; Anderson et al., 2017a). Without making this important acknowledgement, clinicians run the risk of reinforcing Deaf people’s history of oppression and/or re-enacting communication difficulties which may have contributed to the person’s mental health concerns in the first place.

### 1.3  Access to evidence-based therapies

At the time of this publication, there have been no large-scale behavioural clinical trials conducted with Deaf signing people and, therefore, there are no evidence-based psychotherapeutic treatments that have been formally validated for this unique population (Anderson & Wolf Craig, 2018; Estrada & Beyebach, 2007; Fellinger et al., 2012; Glickman & Pollard, 2013; Munro et al., 2008; NASMHPD, 2012). In the United States, there have been many descriptive accounts of how to best serve Deaf therapy clients who use ASL and there is an emerging consensus regarding some best
practices. Much pioneering work was conducted at the Deaf Wellness Center in Rochester, New York (O’Hearn & Pollard, 2008). Among the practices developed there was the creation of filmed teaching stories to illustrate key didactic points from dialectical behaviour therapy, highlighting Deaf actors using native ASL (Pollard et al., 2009). These resources were created, in part, to address the known “fund of information” gap that many Deaf people in clinical settings demonstrate. Other pioneering work was conducted by Neil Glickman and colleagues at the State Hospital Deaf Unit in Westborough, Massachusetts (Glickman, 2009b) and later at PAHrtners Deaf Services in Glenside, Pennsylvania (Glickman, 2017). These efforts culminated in a staff training manual (Glickman, 2017) that illustrated key strategies for therapeutic relationship-building and cognitive behavioural therapy. The intervention development work described in this article drew on these pioneering efforts.

In the past 15 years, there have been some international efforts to evaluate the utility of evidence-based psychotherapies with Deaf and hard of hearing populations—a qualitative interview study of constructionist therapy in Australia (Munro et al., 2008); a one-arm pilot of dialectical behaviour therapy in Australia (Davidson et al., 2012); a multiple case study of solution-focused therapy in Spain (Estrada & Beyebach, 2007); a small randomized controlled trial of assertiveness group training for social anxiety disorder in Iran (Ahmadi et al., 2017); and a randomized controlled trial of a cognitive behavioural therapy self-help program for individuals with acquired hearing loss in the Netherlands (Gamefski & Kraaij, 2012).

1.4 | Research objectives

To begin to address the lack of Deaf-accessible evidence-based treatments in the United States, the driving aim of our work has been to develop and formally evaluate an integrated trauma/SUD counselling approach for Deaf ASL users. Given the linguistic, developmental, and cultural considerations described above, it was especially important to create access to an intervention that educates and supports clients to develop a toolbox of coping skills that simultaneously target trauma and addiction. The present article describes our initial intervention development work (2014–2015), as well as a single-arm pilot study (2015–2018) that evaluated the feasibility, acceptability, and preliminary clinical efficacy of our prototype intervention—Signs of Safety.

2 | METHODS

2.1 | Selection of base intervention

In 2014, the first author assembled a team of Deaf and hearing researchers, clinicians, filmmakers, actors, artists, and Deaf people in recovery to develop Signs of Safety. Signs of Safety is a Deaf-accessible toolkit to be used with Seeking Safety (Najavits, 2002; www.seekingsafety.org)—an existing, effective, widely-adopted protocol for trauma and addiction (Allen et al., 2016).

Seeking Safety is a manualized, cognitive behavioural counselling model that prioritizes clients’ personal safety, including making life changes such as sobriety, addressing suicidal ideation and self-harm, and leaving dangerous relationships (Najavits, 2002). Seeking Safety includes 25 present-focused treatment topics, each engaging clients in themes relevant to trauma and addiction, and helping them to learn a specific skill to target symptoms of both disorders (e.g., “Coping with Triggers,” “Honesty,” “Recovery Thinking,” and “Asking for Help”). The skills are divided into four content areas: behavioural, cognitive, interpersonal, and case management. The evidence-base on Seeking Safety includes positive outcomes from a number of pilot studies, randomized controlled trials, multisite trials, and implementation studies (Lenz et al., 2016; Najavits & Hien, 2013). A recent government analysis indicates that it is in the top three of 23 SUD models in terms of cost–benefit, outperforming motivational interviewing and relapse prevention (Washington State Institute for Public Policy, 2019).

Seeking Safety has been used successfully with diverse populations, translated into 14 languages, and aligns with many recommended practices for Deaf-friendly treatment—for example, emphasis on skill-building and psychoeducation, structured sessions, case management, a focus on the here-and-now, empowering strength-based work, and working “one-down” (Glickman, 2013, 2017). More importantly, among available evidence-based therapies for trauma and addiction, Seeking Safety is the only appropriate option to adapt for Deaf persons who present with language delays given its present-focus (i.e., no need to retell the trauma narrative) and reliance on simple coping skills (Anderson & Wolf Craig, 2018; Hall et al., 2017). The coping skills are practical and easy to understand, and most can be represented with visual aids or illustrated through filmed stories depicting Deaf actors modelling coping behaviours or self-talk.

Each Seeking Safety session follows a four-part structure, as outlined in Figure 1: (1) a brief check in; (2) an inspirational quote related to the current topic; (3) discussion and active practice of a safe coping skill; and (4) a brief check out to review what was learned, identify whether clients had any problems with the session, and help clients choose a coping skill “commitment” (i.e., homework) to complete before the next session.

Seeking Safety can be conducted with low or no-literacy clients in an informal manner (e.g., the counsellor summarizes the content and encourages discussion and rehearsal; Najavits, 2007). However, such implementation has typically occurred when most of the clients in a counselling group are able to read, and just one or a few are unable to. Moreover, Seeking Safety’s client materials are in written English, and, therefore, do not target the unique needs of many signing Deaf clients (Anderson et al., 2016; Glickman & Pollard, 2013). The Signs of Safety toolkit was designed to overcome these barriers via a supplemental counsellor guide and Deaf-accessible client materials, as described below.

2.2 | Intervention development process

To develop the prototype Signs of Safety toolkit, our multidisciplinary Deaf-engaged team first reviewed the counsellor guide and client
materials for each of Seeking Safety’s 25 topics. The team identified “key learning points” that clients should learn and retain following the review of each topic in session. We then followed National Institute on Drug Abuse (NIDA) behavioural therapy development approaches (Rounsaville et al., 2001) and recommended principles for creating Deaf-accessible interventions (Glickman, 2013, 2017; O’Hearn & Pollard, 2008; Pollard et al., 2009) to develop the following client materials:

- **ASL Teaching Stories** on digital video for all 25 Seeking Safety topics, which present key learning points portrayed by Deaf actors. During each counselling session, clients watch a 5- to 10-min episode from this “psychoeducational soap opera” to observe the struggles and successes of four recurring characters in recovery from trauma and/or addiction. The script for each teaching story included dialogue between characters, as well as non-linguistic modelling of coping skill use.

- **Twenty-five inspirational quotations** by Deaf people were paired with each Seeking Safety topic, performed in ASL by a Deaf poet, and filmed; for example, “Life has plenty of potholes but we must drive past with good tires.” - Suzanne Stecker.

- **A select number of visual handouts**, which present information using plain English text and visual aids created by Deaf artist, Michael Krajnak. Most English text is presented in ASL word order (i.e., ASL gloss), and many of the visual aids include two-dimensional representations of ASL vocabulary.

Our team also developed a supplemental counsellor guide to support clinicians in modifying Seeking Safety for Deaf ASL users, including helpful tips for working with Deaf persons, ASL translations of key Seeking Safety vocabulary, how issues raised by each Seeking Safety topic interact with Deaf experience, and Deaf-related examples of difficult cases.

Given the heterogeneity of the Deaf community, Signs of Safety was designed to be accessible to culturally Deaf, hard of hearing, late-deafened, and Deaf blind people. The materials in the client toolkit are intended to be easily understood by Deaf people with various cognitive and linguistic skill levels. For example, visual handouts are comprised of highly simplified English text with visual aids, with the goal that clients can rely on English only, pictures only, or a combination of both. The handouts are designed with a minimalist approach in high-contrast black and white, appropriate for use with Deaf individuals with low vision. The ASL Teaching Stories include a mix of ASL dialogue between characters to demonstrate interpersonal coping skills, ASL self-dialogue (i.e., “self-talk”) to demonstrate cognitive coping skills, and gestural “role-plays,” which attempt to demonstrate behavioural coping skills without any reliance on language. That being said, Seeking Safety and Signs of Safety are clinical tools that are only as effective as the clinicians who utilize them. The success of any counselling approach is highly dependent on the ability of the clinician to match the communication skills and cognitive level of their clients, whether through modelling, role-play, gesture, drawing, or other creative techniques.
2.3 | Single-arm pilot study

Conducted from 2015 to 2018, this single-arm pilot study generated data on feasibility (e.g., attendance, retention, rate of enrolment, fidelity, and assessment procedures), participant satisfaction, and preliminary clinical outcomes (e.g., PTSD symptoms, substance use, and coping self-efficacy). Participants received Seeking Safety supplemented by the experimental Signs of Safety toolkit.

2.3.1 | Recruitment

We recruited 15 Deaf adults from Massachusetts. An a priori sample size of 15 was selected based on recommendations for stage IA behavioural therapy research—“a small number of cases chosen openly and without a control condition” (Rounsaville et al., 2001, p. 140)—as well as for feasibility (i.e., the principal investigator’s [PI’s] ability to provide 25 sessions of the intervention to all participants).

Participants were recruited via advertisements posted on Deaf-related email listservs and social media pages, and disseminated through agencies, clinicians, and case managers who serve Deaf people in Massachusetts. Recruitment materials were presented in both written English and ASL digital video. Recruitment materials directed interested individuals to contact the PI via email or videophone, the standard telecommunication device for the Deaf. Following this first contact, the PI scheduled a one-hour videophone screening call.

2.3.2 | Screening and enrolment

The PI, an ASL-fluent licensed psychologist, conducted structured screening interviews via videophone. Inclusion criteria were as follows: age 18 or above; Massachusetts residency; self-identified hearing status of Deaf or hard-of-hearing; self-identified primary communication mode of ASL; current PTSD as measured by the Clinician-Administered PTSD Scale for DSM-5; past-month substance abuse screen as measured by the Alcohol Use Disorders Identification Test and Drug Use Disorders Identification Test; willingness and ability to attend weekly individual study sessions in Worcester, MA, or Boston, MA; videophone access; and psychiatric stability (i.e., no active psychosis or suicidal intent).

The only exclusion criteria were self-identified membership in the following special populations: adults unable to consent or prisoners. Exclusion criteria were minimal in order to recruit a sample of Deaf adults who were diverse with respect to gender, age, race, English literacy, PTSD and SUD onset, type(s) of trauma experienced, and type(s) of substances used. Eligible individuals were scheduled for an in-person informed consent session with the PI. To supplement the informed consent process, study procedures, potential risks and benefits, and additional study information were described directly in ASL.

2.3.3 | Intervention delivery procedures

Enrolled participants were offered 25 weekly individual Seeking Safety counselling sessions. Although prior Seeking Safety trials have reported positive outcomes using a 12-session, partial-dose treatment protocol (e.g., Hien et al., 2015), we chose to implement a 25-session protocol to inform future intervention development work by collecting comprehensive participant feedback on all 25 Seeking Safety topics.

Counselling sessions were provided by the PI, who was certified to conduct Seeking Safety for research. (Note: Certification is only required for research and optional otherwise.) Participants could choose between two sites based on preferred location; both sites were counselling offices in public mental health agencies. Sessions were conducted weekly for 1 h, covering one of the 25 Seeking Safety modules, supplemented by the prototype Signs of Safety toolkit materials (i.e., ASL quotations, ASL Teaching Stories, and visual handouts). We chose to use individual modality due to known barriers of group participation for members of small, close-knit communities (e.g., lack of anonymity and confidentiality concerns).

2.3.4 | Measures and assessment procedures

We collected data on key aspects of feasibility and acceptability (see details in Table 1).

<table>
<thead>
<tr>
<th>Component of feasibility/acceptability</th>
<th>Operational definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screening</td>
<td>Number of individuals screened per month</td>
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<tr>
<td>Recruitment</td>
<td>Proportion of eligible individuals who enrolled in the study</td>
</tr>
<tr>
<td>Retention</td>
<td>Proportion of enrolled participants who completed the study</td>
</tr>
<tr>
<td>Participant adherence</td>
<td>Receipt of study intervention (i.e., attendance, reported comprehension of treatment materials)</td>
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<tr>
<td></td>
<td>Rate of homework completion between sessions</td>
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<tr>
<td>Participant satisfaction</td>
<td>Seeking Safety End of Session Questionnaire (each session)</td>
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<td></td>
<td>Seeking Safety End of Treatment Questionnaire (end-of-treatment timepoint)</td>
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<tr>
<td></td>
<td>Client Satisfaction Questionnaire (end-of-treatment timepoint)</td>
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<tr>
<td>Fidelity</td>
<td>Study clinician’s integrity to the intervention protocol</td>
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<tr>
<td>Assessment process</td>
<td>Duration of assessment sessions</td>
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<td></td>
<td>Proportion of planned assessments completed</td>
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<td>Reported participant burden of the assessment process</td>
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</table>
To assess treatment fidelity, all counselling sessions were videotaped. A random sample of tapes (two sessions per participant) were reviewed for fidelity to the Seeking Safety and Signs of Safety model. Fidelity ratings were conducted on an ongoing basis by a Deaf mental health counsellor on our research team, who had been certified as a Seeking Safety fidelity rater. Fidelity ratings were conducted using the validated Seeking Safety Adherence Scale (Najavits, 2003) and additional questions from a prototype Signs of Safety Fidelity Scale. This supplemental measure evaluated the appropriate delivery of Signs of Safety toolkit materials, as well as clinical approaches that respect and validate Deaf people's cultural, developmental, and linguistic needs.

Participants were evaluated with a preliminary assessment battery that measured trauma, PTSD, substance use, functioning and psychiatric symptoms (see Table 2). These clinical outcome data were collected at baseline, throughout the intervention, and end of treatment. Assessments were conducted via videophone by the co-investigator, a Deaf clinical psychologist, who administered all written English questionnaires in ASL. Participants received a total of $60 for completing all assessments ($10 mailed after each completed assessment).

2.3.5 | Data analysis

The objectives of this single-arm pilot study were to demonstrate the following: (1) participants’ acceptance of Seeking Safety and Signs of Safety (e.g., retention, satisfaction); (2) ability to recruit sufficient numbers of the target population; (3) feasibility of intervention delivery with the target sample; and (4) clinically significant participant improvement over the course of the study on at least one of the two primary clinical outcomes (i.e., PCL-5 or BAM). Data were collected via Research Electronic Data Capture (REDCap; Harris et al., 2019; Harris et al., 2009) and analysed using SPSS Statistics Version 26 and ATLAS.ti.

TABLE 2 Preliminary efficacy outcome measures

<table>
<thead>
<tr>
<th>Clinical outcome</th>
<th>Measure</th>
<th>Time point</th>
<th>Screen</th>
<th>Baseline/ pre-Tx</th>
<th>After session 5</th>
<th>After session 10</th>
<th>After session 15</th>
<th>After session 20</th>
<th>After session 25/end-of-Tx</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trauma and PTSD</td>
<td>Clinician-Administered PTSD Scale for DSM-5 (CAPS-5)</td>
<td>X</td>
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<td>Life Events Checklist (LEC-5)</td>
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<td></td>
<td>PTSD Checklist for DSM-5 (PCL-5)*</td>
<td>X</td>
<td>X</td>
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<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td></td>
<td>Trauma Symptom Checklist—40</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Substance use</td>
<td>Alcohol Use Disorders Identification Test (AUDIT)</td>
<td>X</td>
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<tr>
<td></td>
<td>Drug Use Disorders Identification Test (DUDIT)</td>
<td>X</td>
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<td></td>
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<tr>
<td></td>
<td>Brief Addiction Monitor (BAM)*</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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</table>

*Measured used to calculate primary clinical outcomes.

We analysed quantitative data using descriptive statistics and clinically significant change scores. Our sample of 15 participants was based on the limited scope of a stage IA pilot study (Leon et al., 2011) and was underpowered to detect a large effect using inferential statistics (e.g., t test, GEE modelling). We thus evaluated clinically significant improvement on our primary outcomes. For PTSD, this was a PCL-5 change score of ±10 points (Bovin et al., 2016). For substance use, we calculated the proportion of the sample that were abstinent by end of treatment or evidenced clinically meaningful reduction in percent days of substance use by the end of treatment. We used the Reliable Change Index (RCI), which is computed by dividing the difference between the pretreatment and posttreatment scores by the standard error of the difference between the two scores (Jacobson et al., 1984; Ogles et al., 2001). An RCI greater than 1.96 is clinically significant (a change of that magnitude would be unlikely based solely on measurement unreliability). Conversely, an RCI score of 1.96 or less could have occurred just due to measurement unreliability.

Participants who completed at least six sessions of treatment (i.e., the “minimum dose” of Seeking Safety; Najavits et al., 1998) were included in preliminary outcome analyses (n = 10). Participants were evaluated for changes in PTSD and substance use from baseline to their most recently available follow-up assessment.

3 | RESULTS

3.1 | Sample characteristics

Participants were 10 women, four men, and one transgender male. Mean age was 36 years (range 21 to 58 years). Thirteen participants (86.7%) identified as white non-Hispanic/Latino; one as white Hispanic/Latino; and one as Asian-American. Half identified as heterosexual (n = 8, 53.3%); four as bisexual; two as gay/lesbian; and one as “other.” One participant held a master’s degree; three had bachelor’s degrees (20.0%); six had attended some college (40.0%);
and five (33.3%) completed their education after graduating from high school. Half of the sample was employed \((n = 8, 53.3\%); six were receiving Social Security benefits (40.0\%); one was a full-time student.

All 15 participants identified as Deaf. Fourteen participants (93.3\%) reported ASL as their preferred language; two (13.3\%) preferred Pidgin Signed English (a contact language between ASL and Signed English); and one preferred written English (Note: This question allowed multiple response options). Twelve participants (80.0\%) had hearing parents; two had Deaf parents (13.3\%); one had both. Seven participants (46.7\%) had attended a school for the Deaf; three (20.0\%) attended a mainstream hearing school; and three (20.0\%) had attended both.

Eleven participants reported a lifetime history of physical assault (73.3\%); 11 reported a transportation accident (73.3\%); eight reported sexual assault (53.3\%); seven reported another unwanted or uncomfortable sexual experience (46.7\%); and six reported an “other very stressful event or experience” (40.0\%). “Other” events included witnessing parent substance use, living through a parental extramarital affair, and being left alone in the hospital as a child. There were a few Deaf-specific events reported as traumatic—being dropped off at Deaf residential school at a young age, ongoing problems with communication in a hearing world, and experiences of discrimination and oppression as a Deaf person (i.e., “audism”).

### 3.2 | Feasibility and acceptability

#### 3.2.1 | Screening, recruitment, and retention

Between May 2015 and September 2017, there were 14 months of open, rolling recruitment (based on availability of counselling slots with the PI). See CONSORT diagram (Figure 2) for detailed rates of screening, eligibility, recruitment, and retention. The full 25-session protocol required an average of 41 weeks to complete (range = 31–54 weeks), including cancellations for illness, transportation, holidays, and vacation.

#### 3.2.2 | Participant adherence

Participants who received treatment \((n = 13)\) attended an average of 16.9 sessions (SD = 9.9). An average of 7.1 sessions were cancelled and rescheduled (SD = 6.6); an average of 0.9 sessions were no-showed and rescheduled (SD = 1.2). Treatment receivers reported that they understood the experimental Signs of Safety toolkit materials at 93.6\% of their counselling sessions (out of a total 219 sessions). They completed between-session homework 76.4\% of the time.
3.2.3 | Participant satisfaction

Across data from 219 counselling sessions, treatment receivers reported moderate-to-high levels of satisfaction with the Seeking Safety model and prototype Signs of Safety toolkit. See Table 3 for details. The one exception was relatively low rates of perceived helpfulness with drug or alcohol use.

According to results from the Client Satisfaction Questionnaire, all participants reported that the quality of services was “good” or “excellent,” that they were satisfied with the amount of help received, and that the treatment helped them deal more effectively with their problems. Nearly three-quarters (71.4%) felt that most or all of their treatment needs had been met. Nearly all (85.7%) would recommend the treatment to friends in need of help for PTSD or SUD.

One participant noted, “there was nothing that I disliked about the treatment ... I thought it was great.” Another stated, “The best part of the treatment was learning to deal with triggers.” Two participants reported that they would have liked to be offered more sessions than the 25-session protocol—“the treatment should be contingent upon the person's stage of sobriety – someone who is not yet sober or recently sober would benefit from more sessions, someone who has been sober a long time would benefit from fewer sessions.” Another participant felt that the program was too limited in scope (i.e., too much time spent focused on SUD issues) and too highly-structured for their needs. However, this same participant also stated, “The program is very important to the Deaf community. Very important, and very needed.”

Table 3: Results from end-of-session questionnaires (n = 219 counselling sessions)

<table>
<thead>
<tr>
<th>Question</th>
<th>Mean level of helpfulness (standard deviation) possible range: 0 = Not at all to 3 = A great deal</th>
</tr>
</thead>
<tbody>
<tr>
<td>How helpful was today's session for you, overall?</td>
<td>2.65 (0.58)</td>
</tr>
<tr>
<td>In today's session, how helpful was the topic?</td>
<td>2.57 (0.62)</td>
</tr>
<tr>
<td>In today’s session, how helpful were the handouts? (both original and visual handouts)</td>
<td>2.26 (0.91)</td>
</tr>
<tr>
<td>In today's session, how helpful was the video? (i.e., ASL Teaching Story)</td>
<td>2.15 (0.85)</td>
</tr>
<tr>
<td>In today’s session, how helpful was the ASL quotation?</td>
<td>2.25 (0.86)</td>
</tr>
<tr>
<td>In today’s session, how helpful was the counselor?</td>
<td>2.79 (0.49)</td>
</tr>
<tr>
<td>How much did today's session help with your PTSD?</td>
<td>2.11 (0.96)</td>
</tr>
<tr>
<td>How much did today's session help with your drug or alcohol use?</td>
<td>1.39 (1.11)</td>
</tr>
<tr>
<td>How much do you think you will use what you learned in today’s session in your life?</td>
<td>2.60 (0.66)</td>
</tr>
</tbody>
</table>

Indeed, participants felt that Signs of Safety was an important development for the Deaf community—“I loved this program ... I want to share all the information I learned with everyone in the Deaf community.” They expressed excitement about the creation of “videos that had all Deaf actors and good signing.” They reported mixed feelings about the ASL quotations—for some, they were reported as the best part of treatment; for others, they were “still too English, not easy to understand conceptually.” Despite general enthusiasm, participants also commented on the prototype nature of the materials—“videos need editing,” “the videos were good but actors needed more rehearsal time, need to improve the translation of quotes, elaborate on the meaning of concepts, change the questions of check-in and check-out to be more clear and ASL-friendly, handouts need to be changed to be more ASL-friendly as well.”

Participants provided vital feedback for producing an improved version of the Signs of Safety toolkit. Suggestions included revising ASL translations of certain recovery concepts; making specific plot changes in the ASL Teaching Stories to better reflect the process of recovery from SUD and PTSD; changing the gender of the counsellor character; and representing greater diversity with respect to age and sexual orientation of ASL Teaching Story characters.

3.2.4 | Treatment fidelity

Seventeen sessions were rated for the PI’s integrity to the counselling protocol. Two participants' sessions were not rated due to a dual relationship between participant and fidelity rater—an example of small community dynamics manifesting in clinical research. For remaining participants, two sessions were randomly selected for review—one between sessions 1 and 12, and one between sessions 13–24. Overall fidelity was strong—an average of 2.53 on a 0- to 3-point scale, with a tight range of scores between 2 and 3 per session.

3.2.5 | Assessment process

All planned assessments were successfully completed. One barrier arose if an assessment was cancelled and rescheduled beyond the next counselling session date. When this occurred, the counselling session was postponed to accommodate the new assessment schedule, disrupting the natural flow of the counselling process. Regarding assessment burden, participants reported that compensation should be increased to more fairly reflect the time required to complete assessments: screening (11–35 min); baseline (35–60 min); mid-treatment (20–40 min); and end-of-treatment (40–60 min).

3.3 | Preliminary clinical outcomes

Results showed clinically meaningful reductions in PTSD severity and alcohol use frequency from baseline to immediate post-treatment (Figure 3). Participants who received the “minimum dose” of Seeking
Safety (i.e., at least six sessions; \(n = 10\)) exhibited a 9.9 point mean reduction on the PTSD Checklist for DSM-5 (PCL-5), aligning with the 10-point clinically meaningful improvement on this measure (Bovin et al., 2016).

Frequency of alcohol use decreased by an average of 4.7 days per month across the course of the study. Eight participants (80.0%) were abstinent or evidenced clinically meaningful reduction in past-month alcohol use by the end of treatment (i.e., Reliable Change Index > 1.96), one remained unchanged, and one increased their drinking.

Regarding use of illegal/street drugs or abuse of prescription medications, five participants (50.0%) were abstinent or evidenced clinically meaningful reduction in past-month substance use by end of treatment, four remained unchanged (40.0%), and one evidenced a clinically meaningful increase in use. Average days of drug use across the sample increased from baseline to immediate post-treatment by approximately 1.2 mean days per month (not clinically significant). This increase was driven by participant-reported marijuana use and is likely due to the legalization of recreational marijuana mid-study. Three participants (30.0%) reported increases in marijuana use from baseline to follow-up; one reported no marijuana use at baseline, but 16 to 30 days of marijuana use at follow-up, likely driving the finding described above.

4 | DISCUSSION

This article describes the first study of its kind—the initial development of a Deaf-accessible counselling toolkit for trauma and addiction and the preliminary evaluation of this prototype via a one-arm pilot study. Despite the small, 10-participant sample in our preliminary analyses, results indicated clinically significant reductions in PTSD symptoms and alcohol use frequency for the Seeking Safety/Signs of Safety model. Drug use frequency did not change significantly—likely attributable to the mid-study legalization of recreational marijuana in Massachusetts. The Deaf population is vulnerable to high rates of marijuana use (Anderson et al., 2018) and some of our participants increased marijuana use during the trial.

Participants reported high levels of satisfaction with both Seeking Safety and the Signs of Safety toolkit and, in most cases, felt that the counselling approach and client materials were helpful to their recovery. However, they gave relatively low perceived helpfulness ratings to the treatment for reducing substance use in contrast to high rates of perceived helpfulness for reducing PTSD. In general, addiction is harder to treat than PTSD (Najavits et al., 2017); however, this discrepancy is not consistent with previous ratings of Seeking Safety, which have indicated strong positive helpfulness ratings for both PTSD and SUD (e.g., Brown et al., 2007). This finding may, therefore, represent a potential therapist effect, in that the PI who provided study intervention was more strongly trained in trauma treatment than addiction treatment. Future studies that employ multiple counsellors will be able to statistically adjust for therapist effects and better understand the influence of individual counsellors on participant outcomes.

Participants reported that they understood nearly 94% of the Signs of Safety toolkit materials presented to them, including ASL quotations, ASL Teaching Stories, and visual handouts. We feel that this is a strong starting place from which to build, especially given the rich qualitative data about how to make Signs of Safety even more effective and engaging for Deaf clients. Of note, one recurring concern surrounded the cultural adaptability of the quotation component of each Seeking Safety session—in which the counsellor presents an inspirational quotation and asks the client to state the main point. Despite our selection of Deaf-created quotations that were presented in ASL video, participants often commented that the practice of interpreting quotations is a “very hearing thing to do.” Instances of such differences between hearing culture and Deaf culture have been written about in depth (e.g., Hoffmeister & Harvey, 1996; Ladd, 2003; Lane, 2005; Lane et al., 1996), yet specific references to the applicability of inspirational quotations have not previously appeared in the literature. Our team is currently investigating other visually-oriented options that may be an appropriate substitute for this Seeking Safety component.

We must also consider the influence of small community dynamics on our results, especially concerns about confidentiality in a close-knit community (Anderson et al., 2017a, 2017b; Cerulli et al., 2015; Mastrocinque et al., 2015). One clear example of this influence was when dual relationships were discovered between research team members and participants, and study procedures needed to be modified to protect participants’ privacy. In these instances, we were...
able to track the impact of small community dynamics on the conduct of our study. However, there are likely other instances that arose of which we are not aware—for example, eligible individuals who refrained from contacting the study team due to privacy concerns. One potential remedy for this barrier will be to employ multiple Deaf community members in the same role so that they can substitute for each other when conflicts-of-interest arise. Another remedy will naturally occur as this program of research matures and expand our recruitment and enrolment from a local, state-wide community to a nationwide sample.

Regarding treatment retention, 66.7% of our 15 participants received at least six sessions or the “minimum-dose” Seeking Safety; 46.6% were “treatment completers” (i.e., attended half of available sessions or more). Retention was primarily impacted by non-treatment-related factors, including four participants (26.7% of the sample) moving out of state mid-study. That being said, a 25-session protocol that averaged 41 weeks to complete was a substantial commitment and we will consider employing a 12-session, partial-dose protocol in future studies.

The current pilot provided a number of additional methodological “lessons learned” for future Signs of Safety studies. For example, in future work, we will not sacrifice the natural flow of counselling sessions to accommodate a rigid assessment schedule. We will increase the amount of participant compensation for completing assessments while simultaneously streamlining our assessment battery to reduce participant burden. To increase the racial/ethnic diversity of the sample, we will expand recruitment and enrolment outside of Massachusetts, as well as recruit and train a more diverse set of study counsellors.

Next steps will include the redesign and refilming of Signs of Safety toolkit materials based on pilot participant feedback, again using a Deaf-engaged development and production process. This new toolkit will be tested via a pilot randomized controlled trial that will be designed based on the present methodological lessons learned. Additionally, future Signs of Safety studies will leverage recent technologies to enhance study efficiency, widen our range of impact, and reduce small community concerns. These technologies may include the provision of counselling remotely via secure video platforms or conducting assessments via online ASL surveys instead of live interviews. Our overarching goal is to refine our clinical trial methods to meet the changing needs of the Deaf community and benefit from ongoing technological advances so that we can successfully develop and evaluate additional counselling toolkits and therapy adaptations to better support the behavioural health of a wide range Deaf clients.

ACKNOWLEDGEMENTS
This work was supported by the by the National Center for Advancing Translational Sciences (Award Number KL2TR000160) and the National Institute on Alcohol Abuse and Alcoholism (Award Number R34AA026929). The content is solely the responsibility of the creators and does not necessarily represent the official views of the National Institutes of Health.

CONFLICT OF INTEREST
Lisa M. Najavits is Director of Treatment Innovations, which provides training, consultation, and materials related to psychotherapy, including the Seeking Safety model that she developed. The remaining authors declare no conflict of interest.

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